MHRA Approves First Monoclonal Antibody Treatment for COVID-19 in the UK

Following on from a thorough review of the evidence carried out by the MHRA, and recommendation by the <u>Commission on Human Medicines</u> (CHM), the government's independent expert scientific advisory body, the MHRA has approved Ronapreve as the first monoclonal antibody combination product indicated for use in the prevention and treatment of acute COVID-19 infection for the UK.

Developed by Regeneron/Roche, the drug is administered either by injection or infusion and acts at the lining of the respiratory system where it binds tightly to the coronavirus and prevents it from gaining access to the cells of the respiratory system.

<u>Clinical trial data</u> assessed by a dedicated team of MHRA scientists and clinicians have shown that Ronapreve may be used to prevent infection, promote resolution of symptoms of acute COVID-19 infection, and can reduce the likelihood of being admitted to hospital due to COVID-19.

Health and Social Care Secretary Sajid Javid said:

"The UK is considered a world leader in identifying and rolling out life-saving treatments for COVID-19, once they have been proven safe and effective in our government-backed clinical trials."

"This is fantastic news from the independent medicines regulator and means the UK has approved its first therapeutic designed specifically for COVID-19."

"We are pleased to announce the approval of another therapeutic treatment that can be used for to help save lives and protect against COVID-19."

"Ronapreve is the first of its kind for the treatment of COVID-19, and after a meticulous assessment of the data by our expert scientists and clinicians, we are satisfied that this treatment is safe and effective."

"With no compromises on quality, safety and efficacy, the public can trust that the MHRA have conducted a robust and thorough assessment of all the available data."

Source:

GOV.UK